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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/840,125  | 04/24/2001  | Igor Splawski        | 2323-158            | 4235             |
| 6449  | 7590        | 10/03/2003           | EXAMINER            |                  |
| ROTHWELL, FIGG, ERNST & MANBECK, P.C.<br>1425 K STREET, N.W.<br>SUITE 800<br>WASHINGTON, DC 20005 |             |                      | SOUAYA, JEHANNE E   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1634                |                  |

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/840,125

### Applicant(s)

SPLAWSKI ET AL.

### Examiner

Jehanne E Souaya

### Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-30,34-44 and 50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-30,34-44 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12/2001.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Currently claims 26-30, 34-44 and 50 are pending in the instant application. An action on the merits of pending claims follows. Claims 1-25, 31-33 and 45-49 have been cancelled in the preliminary amendment filed 4/24/2001.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 26-30, 34-44, and 50 are rejected under 35 U.S.C. 102(a) as being anticipated by Wei et al (hereinafter referred to as Wei; Circulation, vol. 99; June 1999; pp 3165-3171).

Wei teaches a mutation in the SCN5A gene, E1784K which causes long QT syndrome (see abstract). Wei teaches detecting this mutation in exon 28 of the gene using PCR SSCP and that sequencing revealed a codon change of GAG to AAG (G5349A) (claims 28-30, 34-36, 38-44). Wei teaches analyzing this mutation using site directed mutagenesis and functional studies using a *Xenopus* oocyte expression system (claims 34-36). Wei teaches a nucleic acid comprising a mutation in the wildtype SCN5A gene (G5349A) (claim 26, 27, 37, 50) as well as a nucleic acid which encodes a mutant SCN5A protein with an E to K mutation at codon 1784 (claim 50). Wei further teaches a nucleic acid that would hybridize to mutant but not wildtype

SCN5A under certain conditions (see p. 166, col. 2, "Site Directed Mutagenesis, lines 4-5) (claims 26-27 and 37).

4. Claims 27 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Gellens et al (hereinafter referred to as Gellens, PNAS, vol. 89; pp 554-558, 1992).

Gellens teaches isolating human heart channel cDNA, one of which encodes the wildtype SCN5A polypeptide (referred to as hH1). The wildtype SCN5A cDNA sequence anticipates claims 27 and 37 because the claim does not make clear what "wildtype DNA" the claimed nucleic acids hybridize to. The wildtype SCN5A cDNA would hybridize to the specified nucleic acids comprising a one base pair substitution or a few base pair deletions under certain hybridization conditions while not being able to hybridize to a wildtype DNA (such as KVLQT1 or p53).

5. Claims 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (hereinafter referred to as Wang, Current Opinion in Cardiology, vol. 12, pp 310-320, 1997).

The claims are drawn to a method of assessing a risk in a human subject for long QT syndrome by screening the subject for a mutation in SCN5A and comparing the sequence to wildtype, wherein a mutation in SCN5A is indicative of a risk for long QT syndrome. The claims are not directed to any particular mutation in SCN5A. Wang teaches that mutations in SCN5A are associated with long QT syndrome. Wang teaches identifying 3 different mutation (deletion of KPQ 1505-1507) and two missense mutations in two different families.

#### ***Conclusion***

6. No claims are allowable over the cited prior art.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Jehanne Souaya*

Jehanne Souaya  
Primary Examiner  
Art Unit 1634

*9/30/03*